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Attorney Docket No: 3124.00015

### **REMARKS**

Claims 10, 18-21, and 36-37 are currently pending in the application. Claims 10, 21, and 37 are in independent form.

Applicants' express their gratitude for the courtesies extended by the Examiner during a telephonic interview conducted with the Applicants' representative, Amy E. Rinaldo, on Tuesday, March 6, 2004.

Claims 10-11 and 18 stands rejected under 35 U.S.C. § 112, first paragraph, for failing to enable a person skilled in the art to which it pertains, or with which is most nearly connected to, to make and use the invention. The Office Action states that the specification does not teach that the products can be derived from products found in nature. This phrase has been removed from the claims in order to further prosecution. Reconsideration of the rejection is respectfully requested.

Claims 10-11 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Chinese herbal composition "dzan yu dan." Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Chinese herbal composition "dzan yu dan," as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Chinese herbal composition "dzan yu dan" is used for treating impotence. However, there is no disclosure in the cited reference for a compound that is a vasoactive compound. Instead, the cited composition discloses that male impotence is due to the chronic deficiency of yang (fire) energy in the kidney/adrenal system. The composition is intended to restore yang energy and thus diminish sexual inhibitions. There is no disclosure or suggestion that the composition in the concentrations recited is effective as a vasoactive agent or is an aphrodisiac. Instead, the prior art merely discloses that this composition can be used for male impotence by restoring the yang energy to the individual who ingests the composition. Since there is no disclosure for the claimed composition as claimed in the presently pending independent claims in the concentrations recited, the composition is patentable over the cited prior art and reconsideration of the rejection is respectfully requested.

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Claims 10-11 and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Chinese herbal composition "wu dze tang." Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Chinese herbal composition "wu dze tang," as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action states that the Chinese herbal composition "wu dze tang" is used for treating impotence and/or infertility in men, including erectile dysfunction and low sperm count by including compounds that drive blood flow to the penis and aphrodisiac compounds. However, when read more specifically, there is no disclosure that the Chinese herbal composition "wu dze tang" has a vasoactive effect, thus increasing the blood flow to the penis. Instead all that is disclosed is that the "wu dze tang" composition can treat infertility due to low sperm count with related symptoms of insufficient erection and premature ejaculation. The "wu dze tang" composition further discloses that this particular formulation in conjunction with anal sphincter lock is very helpful in restoring circulation in vigor to the male sexual organs. There is no disclosure that the composition alone will have vasoactive effects or that there is an aphrodisiac included therein. In contradistinction, the presently pending independent claims claim a vasoactive agent and an aphrodisiac that is different and performs a different function than that of the cited reference. Since the cited reference does not disclose or teach the composition of the presently pending independent claims, the claims are patentable over the cited prior art and reconsideration of the rejection is respectfully requested.

Claims 10-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Chinese herbal composition "mi jing tang." Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Chinese herbal composition "mi jing tang," as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action states that the Chinese herbal composition "mi jing tang" is used for treating impotence and/or infertility in men, including erectile dysfunction and involuntary loss of semen and related symptoms. However, when read more specifically, there is no disclosure that the composition has a vasoactive effective effect, nor is there any specific reference to the inclusion of an aphrodisiac in the composition. Instead, all that is disclosed is that the composition is used for treating involuntary loss of semen. There is no disclosure of the composition of the presently pending independent claims. The presently pending independent claims claim a composition including a vasoactive composition and an aphrodisiac. Since the cited prior art does not disclose a composition including a vasoactive compound and an aphrodisiac compound as

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recited in the pending claims, the claims are patentable over the cited prior art and reconsideration of the rejection is respectfully requested.

Claims 21-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Cherksey and the Tri-Bex-500™ and ArginMax™ and the DeLuca et al. patent. Reconsideration of the rejection is respectfully requested.

It is Hornbook Law that before two or more references may be combined to negative patentability of a claimed invention, at least one of the references must teach or suggest the benefits to be obtained by the combination. This statement of law was first set forth in the landmark case of Ex parte McCullom, 204 O.G. 1346; 1914 C.D. 70. This decision was rendered by Assistant Commissioner Newton upon appeal from the Examiner-in-Chief and dealt with the matter of combination of references. Since then many courts have over the years affirmed this doctrine.

The applicable law was more recently restated by the Court of Appeals for the Federal Circuit in the case of ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572,1577, 221 U.S.P.Q. 929 (Fed. Cir. 1984). In this case the Court stated, on page 933, as follows:

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under Section 103 teachings of references can be combined only if there is some suggestion or incentive to do so. The prior art of record fails to provide any such suggestion or incentive. Accordingly we hold that the court below erred as a matter of law in concluding that the claimed invention would have been obvious to one of ordinary skill in the art under section 103."

This Doctrine was even more recently reaffirmed by the CAFC in Ashland Oil, Inc. v. Delta Resins and Refractories, Inc., et al., 776 F.2d 281,297, 227 U.S.P.Q. 657,667. As stated, the District Court concluded:

"Obviousness, however, cannot be established by combining the teachings of the prior art to produce the claimed invention unless there was some teaching, suggestion, or incentive in this prior art which would have made such a combination appropriate."

The Court cited ACS Hospital Systems, Inc. in support of its ruling. This Doctrine was reaffirmed in In re Deuel, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995).

The Office Action has held that the Cherksey patent teaches that Muria Puama is well known to be useful in a pharmaceutical composition for its strong sexual stimulation and libido enhancement. However, as specifically disclosed in the Cherksey patent, Muria Puama is the only pharmacologically significant component of the composition. There is no disclosure for the use of Muria Puama in conjunction with other compounds for creating a libido enhancing composition. The same is true for the Tri-Bex-500™ composition and the ArginMax™

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composition. All of the cited references disclose single compounds that are not disclosed to be used in conjunction with other compounds. The DeLuca et al., patent teaches a variety of compounds that can be used for enhancing sexual function. However, the DeLuca patent does not disclose or suggest using all of the compounds that are recited in the presently pending independent claims. Further, as the DeLuca patent was filed more than three years after the issuance of the Cherksey patent, it can be assumed that since no reference was made for the inclusion of additional compounds not specifically listed in the application, that the addition of such compounds was not contemplated by the inventors of the Cherksey patent. There is no teaching or suggestion in the cited prior art for the composition of the presently pending independent claims. Instead, the prior art discloses specific compounds that can be used for increasing libido. It is respectfully submitted that absent a teaching or suggestion for a combination of compounds as recited in the presently pending claims that the cited prior art references cannot be combined. The Court has held that there must be some teaching or suggestion for the combination of references, merely combining references to formulate the compositions of the presently pending independent claims does not provide a *prima facie* case of obviousness. Since there is no disclosure or suggestion in the prior art for the composition of the presently pending claims, the claims are patentable over the cited prior art and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

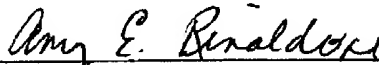
In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

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The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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Dated: May 27, 2004